



DEPARTMENT OF HEALTH AND HUMAN SERVICES

937561
Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive
Suite 101
Baltimore, Maryland 21215
Telephone: (410) 779-5454

02-BLT-11

December 28, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Rose Embrey, Acting President
Haribo of America, Inc.
1825 Woodlawn Drive
Suite 204
Baltimore, Maryland 21207

Dear Ms. Embrey:

The Food and Drug Administration (FDA) attempted to collect samples of jellied candy, which your firm offered for entry into the United States through the port of Baltimore on September 12, 2001, under entry number [REDACTED]. FDA's attempt to collect the samples revealed that the product was moved from Baltimore to New Jersey on or about September 20, 2001, without suitable clearance from the agency. This action is a violation of 21 Code of Federal Regulations (21 CFR), Part 1.90, which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" from FDA.

On September 28, 2001, our office requested the U.S. Customs Service to order redelivery of this shipment of jellied candy. When the product was brought back to Baltimore, Maryland, our office collected samples. The analytical findings found the product to be in compliance. The product was ultimately released on November 14, 2001.

Failure to promptly correct this violation and prevent premature distribution of imported product may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of the U.S. Customs Service, such as in a bonded warehouse. You will be responsible for all costs incurred for secured storage.

Within fifteen (15) working days of receipt of this letter, please notify our office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step taken to prevent recurrence of the violation.

Page 2 – Ms. Rose Embrey, Haribo of America, Inc.
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Your response should be sent to the Food and Drug Administration, Dundalk Marine Terminal Resident Post, 2700 Broening Highway, Dundalk, Maryland 21222, to the attention of Patricia Travers, Compliance Officer. Ms. Travers may be reached at 410-631-0322, extension 15.

Sincerely,

A handwritten signature in black ink, appearing to be 'LB' with a stylized flourish.

Lee Bowers
Director, Baltimore District

*Import not to be subject
for FDA inspection*